IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re patent application of:	Hai H. Trieu	) From an Action by Examiner) Bruce E. Snow
Serial No.:	10/717,684	)
Filed:	December 6, 2002	) Group Art Unit:) 3738
For:	SYSTEMS AND TECHNIQUES FOR INTERBODY SPINAL STABILIZATION WITH EXPANDABLE DEVICES	)
Docket No.:	4002-3269	)

BRIEF OF APPLICANT TRIEU

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Notice of Appeal electronically filed with the United States Patent Office on November 10, 2008, in connection with the above-indicated application, an Appeal Brief according to 37 CFR 41.37 is provided with a credit card payment in the amount of the requisite fee of $510 for a large entity. The Commissioner is authorized to grant any required extensions of time, and charge any fee deficiency or credit any overpayment to Deposit Account No. 23-3030, but not to include issue fees.

I. REAL PARTY IN INTEREST

Per 37 CFR §41.37(c)(1)(i), the real party in interest is Warsaw Orthopedic, Inc., assignee of the application on appeal.

II. RELATED APPEALS AND INTERFERENCES

Per 37 CFR §41.37(c)(1)(ii), the applicants' legal representative, and on information and belief the applicants and the assignee, are unaware of any related appeals or interferences which may be related to, directly affect, or be directly affected by or have a bearing on the Appeal Board's decision in the present appeal.

III. STATUS OF CLAIMS

Per 37 CFR §41.37(c)(1)(iii), claims 1-34 and 72-73 are pending. Claims 35-71 are cancelled. Claims 3-5, 18, 28-29, 31-32, and 34 are withdrawn. Claims 1-2, 6-17, 19-27, 30, 33, and 72-73 stand rejected, and are being appealed on the grounds further explained below.

IV. STATUS OF AMENDMENTS

Per 37 CFR §41.37(c)(1)(iv), no amendments have been filed subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Per 37 CFR §41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is included in this section.

Independent claim 1 is directed to a method for intervertebral stabilization, comprising accessing a disc space between vertebral bodies (*reference numbers V1, V2; page 2, lines 25-28; page 7, lines 8-11, 16-20, 24-29; page 8, lines 4-7, 24-29; page 9, line 6; page 10, line 31-page 11, line 5; page 11, lines 20-21; page 13, lines 20-29; page 13, line 34-page 14, line 2; page 14, lines 14-15; page 15, lines 21-24; page 16, lines 3-15, 19-34; page 17, lines 1-5; page 17, line 34-page 18, line 3; page 18, lines 6, 19-23; page 19, lines 10-27; page 21, lines 21-23; page 22, lines 13-15; page 23, lines 5-8, 10-12; page 23, line 33-page 24, line 2; page 24, lines 4-6, 17-20; page 25, lines 4-6, 12-14; page 26, lines 6-9; page 28, lines 3, 8-15; page 30, lines 4, 19-21; page 36, lines 4-8*); delivering an expandable device (*reference characters 30, 130, 230, 330, 400, 410, 420, 440, 450, 460, 470, 480, 530, 630, 700, 720, 740, 760, 770, 800; page 2, lines 2-11, 22-28, 30-32; page 7, lines 8-11; page 7, line 16-page 8, line 2; page 8, lines 4-7; page 8, line 24-page 9, line 9; page 10, lines 31-34; page 11, lines 18-21; page 13, lines 19-29; page 14, lines 12-15; page 15, lines 9-10, 21-24; page 16, line 4- page 17, line 12; page 17, line 34-page 18, line 3; page 19, lines 10-21; page 21, lines 21-28; page 22, lines 13-21; page 23, lines 5-18; page 24, lines 4-11, 17-21; page 25, lines 4-18; page 26, lines 6-9; page 28, lines 4, 16-17; page 29, lines 1-3, 16-17; page 30, lines 7-8; page 31, lines 13-14; page 32, lines 1-8; page 33, lines 22-24; page 34, lines 1-6; page 36, lines 4-8*) into the disc space in an unexpanded condition (*page 7, lines 8-11; page 7, line 16-page 8, line 2; page 8, line 24-page 9, line 9; page 10, lines 31-34; page 11, lines 18-21; page 13, lines 19-29; page 14, lines 12-15; page 15, lines 21-24; page 16, line 4- page 17, line 12; page 17, line 34-page 18, line 3; page 19, lines 10-21; page 21, lines 21-28; page 22, lines 13-21; page 23, lines 5-18; page 24, lines 4-11, 17-21; page 25, lines 4-18; page 26, lines 6-9; page 28, lines 4, 16-*

17; page 29, lines 1-3, 16-17; page 30, lines 7-8; page 31, lines 13-14; page 32, lines 1-8; page 33, lines 22-24; page 34, lines 1-6; page 36, lines 4-8); expanding the expandable device (*page 2, lines 11-32; page 7, lines 8-11, 18-20, 29-33; page 8, lines 1-2, 24-31; page 9, line 6-32; page 11, lines 21-32; page 13, lines 19-29; page 14, lines 15-31; page 15, line 31-page 16, line 2; page 16, lines 9-11, 20-22, 30-32; page 17, lines 25-27; page 18, lines 8-10, 19-25; page 19, lines 22-27; page 20, lines 15-17; page 21, lines 29-31; page 22, lines 13-24; page 23, lines 1-4, 19-26; page 24, lines 12-16, 22-34; page 25, lines 26-32; page 28, lines 5-6, 18-20, 23-24; page 29, lines 4-6, 11-15, 18-22; page 30, lines 9-10, 22-24; page 32, lines 6-8, 10-14; page 34, lines 4-6; page 36, lines 4-8*) with an expandable element (*reference character 55, 155, 255, 355, 714, 734, 736, 754, 774, 824; page 2, lines 7-10, 12-14, 16-19, 29-31; page 7, lines 14-23; page 8, line 30-page 9, line 32; page 10, line 1-31; page 11, line 18-page 12, line 1; page 14, lines 12-33; page 17, lines 25-27; page 18, lines 8-10; page 19, lines 3-6, 22-27; page 20, lines 12-17, 24; page 21, lines 11-26; page 22, line 30-page 23, line 4; page 23, lines 10-18, 31-32; page 24, lines 4-16, 22-28; page 25, lines 4-11, 26-33; page 26, lines 26-31; page 28, lines 5-6, 18-20, 23-24; page 29, lines 1-3; page 30, lines 5-6, 9-10; page 32, lines 1-8, 10-11; page 33, lines 23-24; page 34, lines 1-6; page 36, lines 4-6*) to distract the disc space (*page 2, lines 25-27, 29-31; page 7, lines 11-13, 20-23; page 7, line 29-page 8, line 2; page 8, lines 24-29; page 9, line 6-12; page 10, lines 18-20; page 11, lines 18-32; page 13, lines 19-29; page 14, lines 12-31; page 15, lines 21-24; page 15, line 31-page 16, line 2; page 16, line 8-page 17, line 5; page 17, line 30-page 18, line 3; page 19, lines 10-12, 22-32; page 21, line 29-page 22, line 2; page 22, lines 8-11; page 22, line 22-page 23, line 8; page 23, lines 19-26; page 23, line 33-page 24, line 2; page 24, lines 12-20; page 24, line 32-page 25, line 3; page*

25, lines 26-30; page 26, lines 6-9, 22-25; page 28, lines 5-6, 18-20, 23-24; page 29, lines 1-6, 18-22; page 30, lines 5-6, 9-10; page 32, lines 1-8; page 34, lines 1-6; page 36, lines 4-6), said expandable element being a balloon (*reference characters 55, 155, 255, 355, 714, 734, 736, 754, 824; page 2, lines 12-14; page 7, lines 14-23; page 8, line 33-page 9, line 1; page 9, lines 13-14; page 32, lines 10-11*) and said expanding including inflating said balloon with fluid (*page 8, line 33-page 9, line 3; page 9, line 6-9, 13-19; page 10, lines 1-11; page 11, lines 21-32; page 14, lines 15-31; page 18, lines 9-10; page 21, lines 11-15, 29-31; page 22, lines 22-24; page 23, lines 19-21; page 25, lines 26-27; page 28, lines 18-20, 23-24; page 30, lines 17-18; page 32, lines 10-14*); deflating said balloon (*page 9, line 19-21; page 11, lines 33-34; page 13, lines 24-25; page 14, lines 32-33; page 25, lines 32-33*) and removing said balloon from said expandable device and said disc space (*page 11, line 34-page 12, line 1; page 13, lines 24-25; page 14, lines 33-34; page 20, lines 24-25; page 22, lines 8-11; page 23, lines 5-8; page 23, line 33-page 24, line 2; page 24, lines 17-20; page 24, line 34-page 25, line 3; page 25, lines 32-33; page 26, lines 6-9; page 30, line 11*); and placing a motion preserving device (*reference characters 55 and 155 (with filler), 270, 810*) in a cavity of the expanded expandable device (*page 2, lines 31-32; page 10, lines 1-11; page 12, lines 1-4; page 19, line 32-page 20, line 2; page 20, lines 24-33; page 21, lines 1-20; page 26, lines 6-31; page 28, lines 7, 18-22; page 29, lines 24-27; page 31, line 18; page 32, line 9; page 35, lines 17-18*).

Independent claim 19 is directed to a method for intervertebral distraction, comprising accessing a collapsed disc space between vertebral bodies (*reference numbers V1, V2; page 2, lines 25-28; page 7, lines 8-11, 16-20, 24-29; page 8, lines 4-7, 24-29; page 9, line 6; page 10, line 31-page 11, line 5; page 11, lines 20-21; page 13, lines 20-29; page 13, line 34-page 14, line 2;*

page 14, lines 14-15; page 15, lines 21-24; page 16, lines 3-15, 19-34; page 17, lines 1-5; page 17, line 34-page 18, line 3; page 18, lines 6, 19-23; page 19, lines 10-27; page 21, lines 21-23; page 22, lines 13-15; page 23, lines 5-8, 10-12; page 23, line 33-page 24, line 2; page 24, lines 4-6, 17-20; page 25, lines 4-6, 12-14; page 26, lines 6-9; page 28, lines 3, 8-15; page 30, lines 4, 19-21; page 36, lines 4-8); mounting an expandable device (*reference characters 30, 130, 230, 330, 400, 410, 420, 440, 450, 460, 470, 480, 530, 630, 700, 720, 740, 760, 770, 800; page 2, lines 2-11, 22-28, 30-32; page 7, lines 8-11; page 7, line 16-page 8, line 2; page 8, lines 4-7; page 8, line 24-page 9, line 9; page 10, lines 31-34; page 11, lines 18-21; page 13, lines 19-29; page 14, lines 12-15; page 15, lines 9-10, 21-24; page 16, line 4- page 17, line 12; page 17, line 34-page 18, line 3; page 19, lines 10-21; page 21, lines 21-28; page 22, lines 13-21; page 23, lines 5-18; page 24, lines 4-11, 17-21; page 25, lines 4-18; page 26, lines 6-9; page 28, lines 4, 16-17; page 29, lines 1-3, 16-17; page 30, lines 7-8; page 31, lines 13-14; page 32, lines 1-8; page 33, lines 22-24; page 34, lines 1-6; page 36, lines 4-8*) on an expandable element (*reference character 55, 155, 255, 355, 714, 734, 736, 754, 774, 824; page 2, lines 7-10, 12-14, 16-19, 29-31; page 7, lines 14-23; page 8, line 30-page 9, line 32; page 10, line 1-31; page 11, line 18-page 12, line 1; page 14, lines 12-33; page 17, lines 25-27; page 18, lines 8-10; page 19, lines 3-6, 22-27; page 20, lines 12-17, 24; page 21, lines 11-26; page 22, line 30-page 23, line 4; page 23, lines 10-18, 31-32; page 24, lines 4-16, 22-28; page 25, lines 4-11, 26-33; page 26, lines 26-31; page 28, lines 5-6, 18-20, 23-24; page 29, lines 1-3; page 30, lines 5-6, 9-10; page 32, lines 1-8, 10-11; page 33, lines 23-24; page 34, lines 1-6; page 36, lines 4-6*) at a distal portion of a delivery instrument (*reference characters 50, 150, 250, 350, 710, 730, 750, 770, 820; page 2, lines 1-31; page 7, lines 14-23; page 8, line 30-page 9, line 34; page 10, line 1-31; page 11, lines 18-32; page 13, lines*

19-29; page 14, lines 12-33; page 17, line 34-page 18, line 8; page 18, lines 19-23; page 19, lines 3-6, 10-12, 22-27; page 20, lines 12-17; page 21, lines 11-26; page 22, lines 13-21; page 22, line 34-page 23, line 4; page 23, lines 10-18, 27-29; page 24, lines 4-16, 22-28; page 25, lines 4-11, 26-33; page 26, lines 26-31; page 28, lines 16-20; page 29, lines 11-15; page 30, lines 5-6; page 31, lines 1-5; page 32, lines 3-5; page 34, lines 1-3; page 36, lines 2-4); delivering the expandable device into the disc space in an unexpanded condition with the delivery instrument (*page 7, lines 8-11; page 7, line 16-page 8, line 2; page 8, line 24-page 9, line 9; page 10, lines 31-34; page 11, lines 18-21; page 13, lines 19-29; page 14, lines 12-15; page 15, lines 21-24; page 16, line 4- page 17, line 12; page 17, line 34-page 18, line 3; page 19, lines 10-21; page 21, lines 21-28; page 22, lines 13-21; page 23, lines 5-18; page 24, lines 4-11, 17-21; page 25, lines 4-18; page 26, lines 6-9; page 28, lines 4, 16-17; page 29, lines 1-3, 16-17; page 30, lines 7-8; page 31, lines 13-14; page 32, lines 1-8; page 33, lines 22-24; page 34, lines 1-6; page 36, lines 4-8*); expanding the expandable device by expanding the expandable element (*page 2, lines 11-32; page 7, lines 8-11, 18-20, 29-33; page 8, lines 1-2, 24-31; page 9, line 6-32; page 11, lines 21-32; page 13, lines 19-29; page 14, lines 15-31; page 15, line 31-page 16, line 2; page 16, lines 9-11, 20-22, 30-32; page 17, lines 25-27; page 18, lines 8-10, 19-25; page 19, lines 22-27; page 20, lines 15-17; page 21, lines 29-31; page 22, lines 13-24; page 23, lines 1-4, 19-26; page 24, lines 12-16, 22-34; page 25, lines 26-32; page 28, lines 5-6, 18-20, 23-24; page 29, lines 4-6, 11-15, 18-22; page 30, lines 9-10, 22-24; page 32, lines 6-8, 10-14; page 34, lines 4-6; page 36, lines 4-8*) to restore a disc space height (*page 2, lines 8-13, 25-27, 29-31; page 7, lines 11-13, 20-23; page 7, line 29-page 8, line 2; page 8, lines 24-29; page 9, line 6-12; page 10, lines 18-20; page 11, lines 18-32; page 13, lines 19-29; page 14, lines 12-31; page 15, lines 21-24; page 15, line 31-*

page 16, line 2; page 16, line 8-page 17, line 5; page 17, line 30-page 18, line 3; page 19, lines 10-32; page 21, lines 11-15; page 21, line 29-page 22, line 2; page 22, lines 8-11; page 22, line 22-page 23, line 8; page 23, lines 19-26; page 23, line 33-page 24, line 2; page 24, lines 12-20; page 24, line 32-page 25, line 3; page 25, lines 26-30; page 26, lines 6-9, 22-25; page 28, lines 5-6, 18-20, 23-24; page 29, lines 1-6, 18-22; page 30, lines 9-10, 12); removing the expandable element from the expanded expandable device (*page 11, line 34-page 12, line 1; page 13, lines 24-25; page 14, lines 33-34; page 20, lines 24-25; page 22, lines 8-11; page 23, lines 5-8; page 23, line 33-page 24, line 2; page 24, lines 17-20; page 24, line 34-page 25, line 3; page 25, lines 32-33; page 26, lines 6-9; page 30, line 11*); and maintaining the restored disc space height with the expanded expandable device (*page 2, lines 1-5; page 7, lines 8-13, 29-31; page 8, lines 12-29; page 9, lines 6-12; page 9, line 33-page 10, line 11; page 11, line 26-page 12, line 4; page 13, lines 19-29; page 14, line 25-page 15, line 7; page 15, line 21-page 17, line 5; page 17, line 27-page 18, line 3; page 18, lines 4-8; page 19, line 10-page 20, line 2; page 20, lines 17-19, 24-33; page 21, lines 1-10, 31-33; page 22, lines 8-12; page 23, lines 5-9; page 23, line 33-page 24, line 3; page 24, lines 17-21; page 26, lines 6-14; page 30, line 12; page 33, lines 11-13; page 34, lines 22-24; page 36, lines 6-7*).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Per 37 CFR §41.37(c)(1)(vi), all grounds of rejection given in the Final Office Action (FOA) are appealed. In particular, the issues presented to the Board include:

1) Whether claims 1 and 19 (and their dependent claims) comply with the enablement requirement of 35 U.S.C. §112, first paragraph; and

2) Whether claims 19-27, 30 and 33 are not anticipated by U.S. Patent No. 6,582,467 to Teitelbaum.

VII. ARGUMEMTS

Per 37 CFR §41.37(c)(1)(vii), the contentions with respect to each ground of rejection outlined above are presented below for review by the Board.

A. Summary of the Argument

All of the present claims are presented to methods for intervertebral stabilization including accessing a disc space between vertebral bodies, delivering an expandable device to the space and expanding it in the space to distract or restore the height of the space. Examples of the methods, with examples of devices used in them, are shown and described throughout the application. The text and diagrams in the application as filed include information sufficient to permit one of ordinary skill in this art to create and use the claimed methods.

The Examiner erred by considering only part of the application in his analysis of enablement. Moreover, his allegations concerning enablement do not meet the threshold of a viable *prima facie* case for rejection. The minimum information needed for rejection has not been provided, and is not in the record, which alone is enough to reverse the enablement rejection. Along with the demonstration of record that the text and drawings constitute a proper enabling disclosure, these rejections should be withdrawn.

The only reference offered is U.S. Patent No. 6,582,467 to Teitelbaum, and it is only applied to independent claim 19 and claims dependent from it. That reference discloses various

devices for use in intervertebral procedures. However, it does not disclose the entirety of the subject matter in independent claim 19 or any of its dependent claims. One of ordinary skill in this art would not recognize all features of claim 19 and other claims in the Teitelbaum reference, such as restoring a disc height by expanding an expandable device. Also, as with the enablement rejections, the Examiner did not meet his burden of proof on anticipation.

B. Overview of Pertinent Law

1. Enablement

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from *disclosures in the patent coupled with information known in the art* without undue experimentation. *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 77 USPQ2d 1041, 1051 (Fed. Cir. 2005) (emphasis in original, and quoting *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217 (Fed. Cir. 1988). The "invention" is the subject matter of the claim at issue, not a species, embodiment or accused product. A need for experimentation to arrive at the claimed subject matter does not destroy enablement, even if such experimentation is relatively long-lasting or extensive, so long as it is not undue. *See Utter v. Hiraga*, 845 F. 2d 993, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988).

The PTO has the burden to establish all facts and legal conclusions needed for an enablement rejection. *In re Angstadt*, 537 F.2d 498, 190 USPQ2d 214, 219 (CCPA 1976) ("[T]he PTO has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling" (*citing In re Armbruster*, 512 F.2d 676, 185 USPQ 152 (CCPA 1975)). The PTO "bears an initial burden of setting forth a reasonable explanation as to why it believes that the

scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (emphasis added). If these initial burdens are not met, "then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

There is a strong presumption of enablement where the specification teaches how to make and use the invention in terms used in the claims. As the Federal Circuit put it,

> [D]isclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. . . . [A]ny party making the assertion that a U.S. patent specification or claims fails, for one reason or another, to comply with §112 bears the burden of persuasion in showing said lack of compliance.

Fiers v. Sugano, 984 F.2d 1164, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993) (*quoting In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ2d 367, 369 (CCPA 1971); *Weil v. Fritz*, 601 F.2d 551, 555, 202 USPQ2d 447, 450 (CCPA 1979)); *see also Staehelin v. Secher*, 24 USPQ2d 1513, 1516 (BPAI 1992). Accordingly, in a case in which the terms in the claims conform to the terms used in the specification, a necessary part of any enablement rejection is a showing of a "reason to doubt the objective truth" of statements in the application giving enabling support.

"The enablement requirement is met if the description enables any mode of making and using the claimed invention." *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991) (emphasis added). Thus, as long as one mode of making and using the subject matter of the claims is given, enablement exists. Enabling information disclosure

may be found anywhere in the specification, including background information. *See Callicrate*, 77 USPQ2d 1041, 1051-52.

2. Anticipation

A reference does not anticipate a claim unless the reference discloses all of the limitations of the claims. *Kallman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983). A limitation cannot be inherent in a reference unless that limitation necessarily occurs in the reference. It is axiomatic that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

C. No Basis for an Enablement Rejection Exists

The record shows no *prima facie* case of non-enablement for any of the pending claims. Absent that showing, the claims are allowable. *Oetiker*, 24 USPQ2d at 1444. What the record does show is that the creation and use of the entire language of independent method claims 1 and 19 is described in the specification. With no other evidence or reasoning in the record that would cast doubt on the disclosure, and the disclosure spelling out how to use the claimed methods, there is no basis for the enablement rejections in this case.

The Entire Specification Is Relevant to Enablement, Not Just One Structure

The principal issue concerning the enablement rejection is the failure to focus on the full scope of the claims. Instead, the Examiner looked only to subject matter allegedly in one alleged

species of devices. That is incorrect for two reasons. First, the claims concern methods, and so limiting consideration of the specification to certain devices does not maintain focus on the claimed method subject matter. Second, excluding any application disclosure in considering enablement of a claim is not supportable. If the claim language is described and enabled with respect to other parts of the application, that is sufficient for enablement.

The fundamental question here is whether any part of the specification is "off-limits" when considering enablement of an otherwise properly-made claim. Section 112 requires that "[t]he specification shall contain a written description . . . of the manner and process of making and using it . . . ." 35 U.S.C. 112, paragraph 1 (emphasis added). No limitation on "the specification" is stated or implied. The principal goal of the enablement requirement is the enrichment of public knowledge. The knowledge given to the public in a patent is the entire specification, not merely parts of it. The person of ordinary skill in the art will not stop reading the specification after one embodiment, regardless of whether an Examiner believes that the claims should be examined with respect to that one embodiment.

The *Callicrate* decision held that disclosure in the background section of an application provided enough information by themselves to enable a claim feature. That enabling disclosure was noted in the application to be an unfavored embodiment. Nevertheless, it was sufficient for enablement. The present case includes several usable device embodiments in the body of the specification, and delineates methods of using them. The described methods are not included in "background" and they are not denigrated, as was the enabling disclosure in *Callicrate*.

Federal Circuit law (including the above-noted *Wright* and *Fiers* opinions) makes plain that enablement analysis concerns the "claimed invention," that is, "the subject matter sought to

be patented." The pending subject matter is methodology for intervertebral stabilization (claim 1) or distraction (claim 19) including particular actions. However, the Examiner focused only on particular structure. The enablement rejection rests solely on the assertion that one particular structure, in an elected species, does not fit the phrase "expandable motion preserving device," and that no other disclosure in the specification would be considered. The pending rejection does not prove non-enablement of the recited actions in the claimed methods.

As will be discussed further below, steps recited in the independent claims can be performed using the apparatus of Figures 1-7B or other apparatus disclosed in the application. Much of the process description in paragraphs 77-86 of the application (referring to numbers and drawings of Figures 1-7B) is very similar or identical to actions described in paragraphs 87-90 (referring to numbers and drawings of Figures 8A-12B). Paragraphs 107-108 refer to methods useful with "the expandable devices discussed herein," such as items 30, 130, 230 and 330. One of ordinary skill, reading the whole specification, knows that the methods of the claims can be "made" and used with a number of different disclosed structures and others.

Proper enablement exists when the application sets forth information sufficient to allow the person of ordinary skill in the art to create and use the claimed methods. The entire specification, not just that pertaining to an alleged species, must be considered in analyzing enablement. The only statement in the record to bolster the enablement rejection is that the elected embodiment "is not capable of being an expandable motion preserving device." That statement shows that the Examiner limited his consideration of enablement to a small part of the specification. Moreover, an "expandable motion preserving device" is not part of the language of claim 1. The rejection should be overturned.

No Prima Facie Case of Non-Enablement Has Been Made

As noted above, Federal Circuit law holds that a specification that teaches making and using the invention with language corresponding in scope to the words of the claims is enabling, unless there is evidence that casts doubt on the objective truth of the specification. *Fiers*, 25 USPQ2d at 1607. The Examiner has the burden to present that evidence to establish a reason for doubting the specification if he or she wishes to make an enablement rejection. *Wright*, 27 USPQ2d at 1513. The final Office Action did not provide any explanation of why undue experimentation might be necessary to achieve the claimed methods.

The only explanation in the record for the enablement rejections is an allegation that "the elected embodiment shown in figures 1 and 4A is not capable of being an expandable motion preserving device." That allegation is merely a conclusion. It is not evidence that casts doubt on the enabling disclosure, and it does not include any reasoning from evidence allowing that conclusion to be reached. It does not discuss whether any putative experimentation would be undue.

The specification uses the same terms as are in the pending claims, as the Board will see. It explains how to generate and use the claimed methods. It meets the *Fiers* standards for enablement, and therefore puts the burden on the Examiner to cast doubt on the objective truthfulness of aspects of the specification.

The Examiner has not provided an explanation of alleged non-enablement, only the conclusory statement noted above. There is no reasoning provided to "doubt the objective truth" of the specification that describes the claimed methods. This enablement rejection does not reach the threshold of a *prima facie* case, and should be withdrawn for lack of support.

The Claims Meet the Enablement Requirement

Considering the specification and claim language as a whole, all aspects of the independent method claims are enabled. The language at issue ("placing a motion preserving device in a cavity of the expanded expandible device") was in claim 1 as originally filed. That claim language finds parallels and explanations in the specification, which discloses insertion of a motion preserving device within an expanded expandable device.

The "species" on which the Examiner's incorrect consideration of the method claims depended is in Figures 1-7A, with Figures 1-2, 4A-4B, 5A-5B, 6A-6B and 7A-7B showing all or part of that device embodiment (note also pages 7-12, among others, of the specification), and Figures 3A-3B showing an intervertebral space prepared for that device embodiment (note also page 10, line 31-page 11, line 5). Along with the description of that device embodiment, page 10, line 31 to page 13, line 29 discuss methods for using that device and additional disclosure. Page 20, lines 24-33 includes discussion of inserting a motion preserving device, and the specification teaches one of ordinary skill that techniques for one type of expandable device are usable with other embodiments of expandable devices (see, e.g., page 19, line 32-page 20, line 2).

As to claim 1, no question exists concerning enablement for "accessing a disc space between vertebral bodies," which is seen in all of Figures 3A-7B and described in text as noted above. The remaining actions recited in claim 1 will be discussed separately:

delivering an expandable device into the disc space in an unexpanded condition— This action is exemplified in Figures 4A and 4B, as well as several paragraphs in the text as

noted above. The specification notes that the expandable device has an unexpanded configuration for delivery to the operative site in minimally invasive procedures, and is delivered and expanded with the delivery instrument to distract the disc space. It further discusses delivering the expandable devices to the operative site and expanding the expandable devices in situ, for example by a balloon catheter-type instrument having an expandable distal portion about which a collapsed expandable device is positioned. The delivering can be done via recited approaches and using the assistance of given viewing systems. The specification also recites discectomy, endplate and insertion location preparation, placing unexpanded expandable device on delivery instruments and inserting them to the insertion locations. One of ordinary skill in the art is told a way to deliver an expandable device into a disc space in an unexpanded condition, from initial access to and preparation of the site to using a delivery instrument to do the actual delivering.

expanding the expandable device with an expandable element to distract the disc space, said expandable element being a balloon and said expanding including inflating said balloon with fluid— The above summary of specification support shows that the specification identifies an embodiment of item 55 (see also Figures 1-2 and 5A-6B) as a "balloon-like structure" on a shaft through which "fluid or material can be supplied . . . to enlarge or inflate expandable element 55." A particular example is a high-pressure balloon catheter inflatable with air or saline. That disclosure teaches the person of ordinary skill a way to expand a balloon expandable element with fluid. With the disclosure of positioning and securing a collapsed expandable device on the expandable element (e.g. page 7, lines 14-23; page 8, line 30-page 9, line 12), it is sufficient to enable one of ordinary skill to perform the recited action. But this

action is also explicitly explained at page 11, lines 18-32: a fluid is "delivered to expandable elements . . . through a syringe or pump operable to provide sufficient pressure for distraction of the adjacent vertebrae. As the pressure and volume of the respective expandable elements . . . increase, [the] expandable devices . . . are gradually expanded . . . until the desired disc space D1 is achieved."

deflating said balloon and removing said balloon from said expandable device and said disc space— Specification locations for support of this language are noted above. The brief description of Figures 6A-7B address this action succinctly, noting that the figures show the delivery instrument collapsed or deflated (Figs. 6A-6B) and removed from the surgical site (Figs. 7A-7B). The specification instructs one of ordinary skill to deflate the expandable element (e.g. a balloon) and remove it from the now-expanded devices 30, 130 in the disc space. See, e.g., page 11, line 33-page 12, line 4. In another example, one balloon or other expandable element can be used sequentially for two expandable devices, which indicates deflation and withdrawal of the expandable element from an expandable device prior to using it with a second expandable device. See, e.g., page 13, lines 19-29.

placing a motion preserving device in a cavity of the expanded expandable device— "[A] motion preserving device can be inserted into the cavity of the expandable devices 230, 330, as discussed further below." See, e.g., pare 19, line 32-page 20, line 2. The specification instructs that techniques useful with specified devices are also applicable to "other expandable device embodiments discussed herein." See page 19, lines 13-21. Those instructions and others link placing a motion preserving device with the structure of Figures 1-7B to one of ordinary skill in the art, telling him or her how to perform and use the last-recited action in claim 1.

Moreover, as noted above it is incorrect to limit the part of the specification considered in an enablement analysis. Paragraph 112 describes and enables the action of placing a motion preserving device in an expanded expandable device. With the disclosure of the way to perform and use the rest of the actions recited in claim 1 found throughout the application (including Figures 1-7B and related text), claim 1 is fully enabled. Add to that the fact that the "placing" action was originally in claim 1 as filed, and the question of enablement disappears.

There is No "New Matter" in Claim 1

The final Office Action further alleged that "said expandable element being a balloon and said expanding including inflating said balloon with fluid; deflating said balloon and removing said balloon from said expandable device and said disc space" was "new matter." The stated basis for this rejection was the enablement requirement of Section 112, paragraph 1, but the phrase "new matter" seems to suggest that the written description requirement is referred to. Either way, these features of claim 1 were discussed above at length. That discussion establishes that that language is fully supported by the drawings and text of this application, both in terms of enablement and in terms of written description.

Claim 19 Is Also Enabled

The remarks above are equally applicable to independent method claim 19. The Examiner's basis of record for the enablement rejection was applied to claim 19 as well, without further discussion. The incorrect limitation of the specification support considered and the lack of a *prima facie* case all show that the enablement rejection of claim 19 should be withdrawn.

Moreover, the sole ground cited in the record for this rejection concerns an "expandable motion preserving device." That language is not in claim 19.

No Individual Allegations under Section 112 Exist Against Dependent Claims

The Office Action based its enablement and "new matter" rejections solely on features recited in claims 1 and 19. It's Section 112 rejections of the dependent claims must therefore be grounded in the same reasoning. Accordingly, in light of the discussion above, no Section 112 grounds remain for the rejection of the dependent claims.

The Teitelbaum Reference Does Not Anticipate Claims 19-27, 30, or 33

No Prima Facie Case of Anticipation Has Been Made

Claims 19-27, 30 and 33 are not anticipated by the Teitelbaum reference (US 6,582,467). As with the enablement rejections, the record has nothing but a conclusory statement about anticipation. It is "incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *In re Levy*, 17 USPQ2d 1461, 1462 (Board of Pat. App. & Interf. 1990); 37 CFR 1.104(c)(2). The record does not give a *prima facie* case of anticipation, at least because it does not analyze the reference or show any correspondence between it and the claims at all, much less identify where in the reference each part of the recited method is. Applicant is placed in the problematic position of having to guess the PTO's views of the reference.

The PTO did not meet its burden to provide a properly reasoned and supported anticipation rejection. Without such reasoning and support in the record, the rejection cannot

stand. *See, e.g., In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent"). No response is necessary from the Applicant on this ground, since a *prima facie* case of anticipation is not in the record.

Teitelbaum Does Not Anticipate Independent Claim 19 or its Dependent Claims

As best understood, Teitelbaum does not anticipate claim 19 at least because it does not show expanding the expandable device by expanding the expandable element to restore a disc space height, as recited in claim 19. The reference discloses preparing a disc space and adjacent vertebral endplates (column 4, lines 5-14), expanding the disc space with a balloon (column 4, lines 14-17), and placing a stiff plastic or metal delivery sheath in the disc cavity (column 4, lines 18-19; column 3, lines 55-57), separating the vertebrae. An expandable cage mounted on a dual balloon is advanced through that stiff sheath, and expanded (column 4, lines 19-26). After expansion to the inner diameter of the sheath or less, the cage is packed with supporting bone or bone matrix material. The stiff sheath is then removed from around the cage (column 4, lines 26-30), apparently allowing the vertebrae to settle against the cage.

Thus, Teitelbaum's method expands a disc space with one balloon, holds it open with a stiff sheath, and inserts a cage/balloon combination into the sheath. Expansion of the cage by its balloon does not restore a disc space height. The balloon and cage combination remains inside the stiff sheath, away from the vertebrae during expansion. The cage expansion as Teitelbaum discloses cannot have any effect on the vertebrae, because the support sheath around it is holding the vertebrae away from it. The cage only contacts the vertebrae after the sheath is withdrawn at

the end of the procedure. While Teitelbaum expands its cage with a balloon, that expansion does not restore disc height as claim 19 recites. Rather, the reference discloses widening an intervertebral space with a balloon, holding the space open with a sheath, and allowing the vertebrae to settle around a previously-expanded cage.

It is noted that Teitelbaum asserts that its expanded cage may "come into apposition with endplates above and below [and] sharp barbs 12 protrude into the subcortical bone." It also suggests a design for its cage that "permit[s] the superior and inferior surfaces to flatten against the endplate[s]." See column 2, lines 45-53. This disclosure is at odds with the method disclosures of columns 3 and 4, noted above, which describe expansion of the cage in the stiff sheath. Two possibilities for reading those disclosures together arise. First, if the expansion forces the barbed cage against the stiff sheath, the result is either penetration of the barbs into the sheath or the dulling or bending of the barbs by the sheath. Penetration by the barbs means that the cage will come out along with the sheath when the sheath is withdrawn from the vertebral space. Bending or dulling the barbs means that they cannot enter the vertebral endplates when the sheath is withdrawn. In either case, the combination of the barbed cage, the disclosed method of placement and the result is inoperable. The second possibility is that the cage is expanded only to a degree in which the barbs do not contact the sheath. In that case, the removal of the sheath allows the vertebrae to come together, settling against the cage and effectively impaling themselves on the barbs. Similarly, Teitelbaum's language concerning flattening of parts of the cage against vertebral endplates reflects allowing the vertebrae to settle against a cage.

In any event, the noted language of Teitelbaum's column 2 does not disclose restoring a disc height by expanding the cage. Either the disclosure is inoperable in that context, or it

discloses allowing the vertebrae to settle against the cage. These disclosures are not restoring a disc height by expanding, but are releasing previously-spread vertebrae to compress the cage.

The present application specifically notes that its methods require fewer steps and less structure. See, e.g., page 7, lines 29-31 ("Distraction of the disc space with the expansion of the expandable device eliminates requirements for positioning of a distraction device in the disc space to maintain disc space distraction prior to insertion of the expandable device"); page 11, lines 31-32 ("distraction of undistracted disc space D prior to insertion of the collapsed expandable devices 30, 130 is not necessary). Teitelbaum's method disclosure specifically requires a distraction, held open by a sheath, before its device is inserted. It does not explicitly or inherently disclose restoring a disc height by expanding an expandable device, as recited in claim 19.

Other embodiments in the Teitelbaum reference are even further away from the claimed methods. The self-expanding cages are not expanded by an expandable element as recited in claim 19, and the vertical cages similarly do not restore a disc height by their expansion via an expandable element.

Claims 20-33 are dependent from claim 19, and are allowable on that basis and/or on their own merit. For example, claim 26 recites that when expanded the expandable device has a first height adjacent one end and a second height adjacent the other end that is not equal to the first height. That feature is not seen in the Teitelbaum reference. Similarly, Teitelbaum does not show an expandable device tapered between its ends as recited in claim 27. Claim 33 recites positioning a motion preserving device in the expanded expandable device, and removing load supporting elements of the expanded expandable device. Teitelbaum discloses only fusion

cages, and the only material in its expanded cage is bone or similar material for promotion of bone growth in the cage (see column 2, 57-62; column 4, lines 26-29). It does not and cannot show or suggest positioning a motion preserving device in an expanded expandable device. It also does not suggest removing anything from its expanded cage.

VIII. CONCLUSION

For the above reasons, the Examiner's rejections of claims 4, 5, 36-40, 42, 55 and 57-63 under 35 U.S.C. §§112, 102(b) and/or 103(a) are in error and should be reversed. Applicants thus respectfully request reversal of the present rejections and passage of the present application to issuance.

Respectfully Submitted,

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APPENDIX A
Per 37 CFR §41.37(c)(1)(viii)
APPLICANTS' CLAIMS AT ISSUE IN THE APPEAL

1. (previously presented) A method for intervertebral stabilization, comprising:

accessing a disc space between vertebral bodies;

delivering an expandable device into the disc space in an unexpanded condition;

expanding the expandable device with an expandable element to distract the disc space, said expandable element being a balloon and said expanding including inflating said balloon with fluid;

deflating said balloon and removing said balloon from said expandable device and said disc space; and

placing a motion preserving device in a cavity of the expanded expandable device.

2. (original) The method of claim 1, wherein accessing the disc space includes accessing the disc space from a posterior approach.

3. (withdrawn) The method of claim 1, wherein accessing the disc space includes accessing the disc space from an anterior approach.

4. (withdrawn) The method of claim 1, wherein accessing the disc space includes accessing the disc space from a posterior-lateral approach.

5. (withdrawn) The method of claim 1, wherein accessing the disc space includes accessing the disc space from a lateral approach.

6. (original) The method of claim 1, further comprising mounting the expandable device on a distal portion of a delivery instrument before delivering the expandable device.

7. (original) The method of claim 6, wherein the distal portion includes the expandable element, and expanding the expandable device include includes placing polymerizable material in the expandable element.

8. (original) The method of claim 7, placing the motion preserving device includes curing the polymerizable material in the expandable element.

9. (original) The method of claim 1, wherein expanding the expandable device includes inflating the expandable element.

10. (original) The method of claim 9, further comprising mounting the expandable device on the expandable element with the expandable element in a deflated condition before delivering the expandable device.

11. (original) The method of claim 1, wherein expanding the expandable device includes moving a first portion and a second portion of the expandable device away from one another into contact with an endplate of an adjacent one of the vertebral bodies.

12. (original) The method of claim 11, wherein the first portion and second portion are substantially rigid.

13. (original) The method of claim 12, wherein the first portion and the second portion include bone engaging features along outer surfaces thereof.

14. (original) The method of claim 11, wherein the first portion and the second portion extend between a proximal end and a distal end of the expandable device, and when expanded the first portion and second portion form a first height adjacent the distal end and a second height adjacent the proximal end, one of the first and second heights being greater than the other of the first and second heights.

15. (original) The method of claim 14, further comprising orienting the greater one of the first and second heights anteriorly in the disc space.

16. (original) The method of claim 1, wherein the vertebral bodies comprise a concavely curved portion of a scoliotic spinal column segment, and the disc space includes a collapsed height along one side of a midline of the spinal column segment, and expanding the expandable

device restores the collapsed disc space and reduces the scoliotic curvature of the concavely curved portion.

17. (original) The method of claim 1, further comprising:

temporarily supporting the disc space with the expanded expandable device before placing the motion preserving device; and

removing load supporting elements of the expanded expandable device to transfer spinal column loads to the motion preserving device.

18. (withdrawn) The method of claim 17, wherein removing load supporting elements includes degrading the load support elements in situ.

19. (original) A method for intervertebral distraction, comprising:

accessing a collapsed disc space between vertebral bodies;

mounting an expandable device on an expandable element at a distal portion of a delivery instrument;

delivering the expandable device into the disc space in an unexpanded condition with the delivery instrument;

expanding the expandable device by expanding the expandable element to restore a disc space height;

removing the expandable element from the expanded expandable device; and

maintaining the restored disc space height with the expanded expandable device.

20. (original) The method of claim 19, further comprising placing bone filler material in the expanded expandable device.

21. (original) The method of claim 19, wherein the expandable element is positioned in a cavity defined between first and second portions of the expandable device.

22. (original) The method of claim 19, wherein the expandable element includes an interior inflatable with fluid.

23. (original) The method of claim 19, wherein accessing the disc space includes accessing the disc space from an approach selected from the group consisting of: anterior, lateral, posterior-lateral, and posterior surgical approaches.

24. (original) The method of claim 19, wherein expanding the expandable device includes moving a first portion and a second portion of the expandable device away from one another.

25. (original) The method of claim 24, wherein the first portion and second portion are substantially rigid.

26. (original) The method of claim 24, wherein first portion and second portion each extend between a proximal end and a distal end of the expandable device, and when expanded the first

portion and second portion are separated by a first height adjacent the distal end and a second height adjacent the proximal end, one of the first and second heights being greater than the other of the first and second heights.

27. (original) The method of claim 26, wherein the expandable device is tapered between the distal and proximal ends when expanded.

28. (withdrawn) The method of claim 26, wherein the expandable device includes a stepped configuration between the proximal and distal ends when expanded.

29. (withdrawn) The method of claim 19, wherein the expandable device includes a width that is substantially the same in the expanded and unexpanded conditions.

30. (original) The method of claim 19, wherein the expandable device is radially expandable.

31. (withdrawn) The method of claim 19, wherein delivering the expandable device includes orienting a convexly curved anterior wall along an anterior portion of the disc space.

32. (withdrawn) The method of claim 31, wherein the expanded expandable device includes a D shape.

33. (original) The method of claim 19, further comprising:

positioning a motion preserving device in the expanded expandable device; and

removing load supporting elements of the expanded expandable device to transfer spinal column loads to the motion preserving device.

34. (withdrawn) The method of claim 33, wherein removing load supporting elements includes degrading the load support elements in situ.

35-71. (cancelled)

72. (previously presented) The method of claim 1, further comprising delivering a second expandable device in the form of a high-pressure inelastic balloon and placing polymerizable material in said balloon, said second expandable device and said polymerizable material being at least part of said motion preserving device.

73. (previously presented) The method of claim 16, wherein said delivering the expandable device includes placing said expandable device to said one side of said midline.

APPENDIX B
EVIDENCE APPENDIX
Per 37 CFR §41.37(c)(1)(ix)

None.

APPENDIX C
RELATED PROCEEDINGS APPENDIX
Per 37 CFR §41.37(c)(1)(X)

None.